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Olivier Geneste

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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT

PAPER NUMBER

1656

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                       |                                       |  |
|------------------------------|---------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/566,668  | <b>Applicant(s)</b><br>GENESTE ET AL. |  |
|                              | <b>Examiner</b><br>Maryam Monshipouri | <b>Art Unit</b><br>1656               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-40 is/are pending in the application.  
4a) Of the above claim(s) 30-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All    b) ☐ Some    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/6/07</u><br><u>FLC</u> | 6) <input type="checkbox"/> Other: ____  |

Claims 21-40 are still at issue and are present for examination.

Applicants' arguments filed on 8/27/07, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office action are hereby withdrawn.

Claims 21-29 are under examination on the merits. Claims 30-40 are hereby withdrawn as drawn to non-elected invention. Upon review of the previous office action it became apparent that claim 29 which has the same scope as the nucleic acid sequences elected, must have been rejoined with the elected claims 21-28. The examiner regrets said inadvertent error in her previous office action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-29 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

according to previous office action. In traversal of this rejection applicant argues the following: (1) the "Bcl 2 family" is defined in page 2 of the specification. (2) That Bcl-2 family are well known to those skilled in the art and applicant further provides Cory et al. as a representative reference indicating the status of the art with respect to the term "Bcl-2 family" members. Therefore, in view of applicant, said rejection must be withdrawn.

These arguments were fully considered but were found **unpersuasive**. In response to applicant's **first** arguments it should be noted that applicant's definition of the term "Bcl-2 family " members provided in page 2 of the specification is not clear. This is because said term is defined as comprising about 20 proteins including Bcl-2, Bcl-XL and Bcl-W etc. As applicant can appreciate this definition does not define each and every member of Bcl-2 family and merely provides three examples of its members.

With respect to applicant's **second** argument, again even though prior art including Cory et al. provides some examples of said family members it fails to identify all members therein. For example page 648 of Cory et al., column 2 , states that Bcl-2 has at least 20 relatives , including four other anti-apoptotic proteins: Bcl-X<sub>L</sub>, Bcl-w, Al and McII etc. Again this

definition is indefinite because it fails to define the metes and bounds of "Bcl-2 family" members.

Therefore, the rejection remain for the reasons of record in addition to reasons provided above.

Claim 23 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention according to previous office action. In traversal of this rejection applicant argues the following : (1) in page 4 of the specification the term "functional variants" are defined stating that "point mutant" is a "functional variant" of SEQ ID NO:1. According to applicant, functional variants may be obtained by modifications such as additions, deletions, substitutions etc. which conserve the ability of interacting with anti-apoptotic proteins of the "Bcl-2 family".

(2) In example 1 of the specification methods of evaluating interactions of peptides with anti-apoptotic proteins of the " Bcl-2 family" are explained. Therefore, in view of applicant, the description of "point mutant" provides a structural/functional basis to skilled artisan in order to comprehend the genus.

These arguments are also considered and again were found **unpersuasive**. In response to applicant's **first** argument it should be noted that in page 4 of the specification "functional variants" are merely defined by function and said function is unclear because all members of the "Bcl-2 family" are unknown (see 112 second rejection above). Further, applicant's interpretation of what "functional variants" structurally constitute cannot be relied upon because they are not extracted directly from the specification and are subject to different interpretation by the skilled artisan.

With regard to applicant's **second** argument the examiner agrees that methods of determining interactions between peptides and members of "Bcl-2 family" are well established in the prior art but she respectfully disagrees with applicant that the description of the term "point mutant" provides structural/functional basis to comprehend the genus. This is because said genus is neither defined by structure nor by function (see 112 second rejections above). Therefore, in view of the response provided above in addition to those provided previously, the examiner finds no reason to withdraw the rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-29 remain rejected under 35 U.S.C. 102(b) as being anticipated by Shimkets (cited previously) according to previous office action. In traversal of this rejection applicant argues that one of skill in the art could not envision the isolated peptide having the amino acid claimed from the boarder amino acid sequence of Shimkets et al., The identification of this particular interaction domain which allows the formation of homo- and hetero-dimers is not disclosed in Shimkets et al., nor is a procedure to identify such domain. It may not be inferred that the deduced amino acid sequence of Shimkets et al. would function as the isolated species of the instant invention. Therefore, applicant requests withdrawal of the rejection.

This arguments was fully considered but was found **unpersuasive**. This is because applicant is reminded that instantly elected claim 21 (and its dependent claims 22-22, 24-25, 27-29 ), are not directed to an amino acid sequence (or DNA encoding it) consisting of SEQ ID NO:1, but comprising it. The identification procedure of a particular interaction domain

between antiapoptotic proteins and the "Bcl-2 family" proteins through dimerization is not relevant to the elected claims because the instant invention is directed to a product and not a method of making or using it. Once again applicant is reminded that in instant claim he is not claiming an isolated species but a genus of polypeptides comprising SEQ ID NO:1. Therefore the rejection remains for the reasons of record.

Claims 23 and 26 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hammond et al. (cited previously), according to previous office action. In traversal of this rejection applicant argues that Hammond fails to teach a sequence identical to functional variants, including point mutants of SEQ ID NO:1 or a functional portion thereof. According to applicant, Hammond does not disclose an amino acid sequence which forms homo-hetero-dimers and therefore should be withdrawn.

This arguments was also fully considered but was found **unpersuasive**. Applicant is requested to refer to 112 second rejections cited above wherein the term "functional variants" were considered to be unclear. Further applicant is claim 23 (and 26) is not claiming "functional variants" but "point mutants" and the specification did not clearly state that "point mutant" is a type of "functional variant". Furthermore, "forming homo



or hetero dimers" are not recited anywhere in claims 23 or claim 26 and even if it did it would be inherent to the product(s) claimed. Therefore, Hammond reference remains to anticipate the invention.

**No claim is allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center

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(EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*M. Monshipouri*

Maryam Monshipouri Ph.D.

Primary Examiner

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